Title: CARDIAC RHYTHM MANAGEMENT SYSTEM WITH TIME-DEPENDENT FREQUENCY RESPONSE

REMARKS

This responds to the Office Action dated December 29, 2008.

Claims 1, 3, 12-17, 19, 21-22 are amended. No claims are cancelled or added. As a result, claims 1-46 remain pending in this patent application, of which claims 24-38 have been withdrawn by the Examiner.

Information Disclosure Statement

Applicant submitted an Information Disclosure Statement and a 1449 Form on November 16, 2004. Applicant notes the reference listed on page 2, under "Other Documents" has not been initialed by the Examiner. Applicant respectfully requests that an initialed copy of the 1449 Form be returned to Applicant's Representatives to indicate that the cited references have been considered by the Examiner.

8 112 Rejection of the Claims

- Claim 7 was rejected as indefinite on the grounds that claim 3 recites the "QRS complex," while claim 7 recites "a T-wave." The Office Action asserts "[i]t is unclear if the Applicant has additional sensing circuitry to detect the T wave or if the T wave is sensed with the same circuitry that detects the 'QRS complex.'" Applicant respectfully traverses this rejection, as explained below.
 - Claim 1 recites "a sensing circuit for sensing an intrinsic electrical heart signal."
 - Claim 3 recites "the sensing circuit" and notes that "the heart signal" can include a "ORS complex."
 - Claim 7 recites "the sensing circuit," and notes that "the heart signal" can include a
 "T-wave"

One of ordinary skill in the art would understand that a sensed heart signal can include both a QRS complex and a T-wave, and that the same sensing circuit "the sensing circuit" of claims 1, 3, and 7) can be used to detect the same heart signal including both the QRS and T-wave components. Applicant respectfully submits that this is sufficiently clear from the claims as presently worded.

In view of the above, Applicant respectfully requests reconsideration and withdrawal of this rejection of these claims.

As a further note, Applicant previously traversed this rejection, but the present Office Action has not offered any clarification. Accordingly, Applicant is submitting a Formal Request for Interview to obtain enough clarification to expediently resolve this minor wording issue.

- Claims 1, 3, 12-13, 15-17, 19 and 22 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.
 - Regarding claims 1 and 22, the Office Action asserts that it is unclear what element is
 measuring the elapsed time. Accordingly, claims 1 and 22 have been amended to recite
 that the sensing circuit can measure the elapsed time, or that a measurement of the
 elapsed time can be received from another circuit, such as the controller circuit 220.
 - Also, regarding claims 1 and 22, the Office Action asserts that it is unclear what has a
 "frequency bandwidth" being adjusted. Accordingly, claims 1 and 22 have been
 amended to recite that the sensing circuit has a frequency response having the recited
 "frequency bandwidth."
 - Regarding claim 12, the Office Action asserts that it is unclear what element possesses "a
 high[pass] pole frequency." Accordingly, claim 12 has been amended to recite that the
 sensing circuit includes a frequency response having the recited highpass pole frequency.
 - Regarding claims 3, 12-13, 15-17 and 19, the Office Action asserts that it is unclear if all
 three of these signals or at least one of the three is meant. Accordingly, these claims have
 been amended to recite that "at least one" of the three is meant.

In view of the above, Applicant respectfully requests reconsideration and withdrawal of this rejection of these claims. Filing Date: July 10, 2003

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\$102/\$103 Rejections of the Claims

Claims 1-7, 11-23, 39-41 and 43-45 were rejected under 35 U.S.C. § 102(b) for anticipation by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Stotts et al. (U.S. Patent No. 5,161,529). Applicant respectfully traverses.

The Office Action notes:

As to claims 1 and 22. Stotts et al. discloses the modification of the frequency band in the sensing circuit, but is silent whether this change is gradual between the switching. However, the examiner considers the adjustments between the frequency bands to be "gradual adjustment" since the adjustments in the frequency hands are measured and not extreme or drastic.

(Office Action at 5.) Applicant respectfully disagrees that Stotts is silent on whether this change in gradual. In fact, Stotts expressly states that the "shifts in amplifier gain and bandpass characteristic are discrete," (see Stotts col. 5, lines 30-31), meaning that Stotts expressly teaches away from regarding its shifts as gradual. To the extent that the Office Action regards such shifts as gradual, the Office Action's position is objectively unreasonable because it is in direct contravention of the express teachings of Stott.

As an alternative position, the Office Action notes:

In the alternative, although the examiner considers Stotts et al. to disclose a gradual adjustment of the frequency bands above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make gradual adjustments to the frequency bandwidth in order to provide the predictable results of providing a smoother transition between frequency bandwidths and ensuring that signals that might exist between the transition period between the frequency bands can be detected.

(Office Action at 5.) Applicant respectfully submits that the Office Action's reasoning for such an obviousness assertion fails, as explained below. Stotts expressly stated purpose for Stotts' abrupt switching of frequency response is to detect the evoked response to a pacing pulse, that is, the immediately resulting heart contraction following a pacing pulse. Therefore, Applicant respectfully submits that Stotts' discrete switching to a frequency bandwidth suitable for detecting an evoked response substantially immediately following a pace is necessary to accomplish this intended purpose of detecting the evoked response—the discrete switching allows the appropriate frequency response to immediately be in place as needed to detect the evoked response that immediately follows delivery of the pace. Similarly, once the evoked

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response has been detected, there would be no reason for Stotts to delay resuming the frequency response needed to detect other desired cardiac signal artifacts—to keep an inappropriate (i.e., geared toward evoked response detection) frequency response for longer than necessary would only increase the difficulty of detecting other desired cardiac signal artifacts.

Applicant has further amended the claims to recite or incorporate triggering a frequency response that is temporarily less sensitive to detecting evoked and intrinsic events of the heart signal followed by gradual adjustment of the frequency bandwidth of the frequency response as a function of an elapsed time relative to the event, such that the frequency response gradually becomes more sensitive to detecting evoked and intrinsic events of the heart signal, such as described in the present application at page 7, lines 5-11 and elsewhere in the specification of the present patent application. Stotts does not do this, since its frequency response adjustment is intended to make it temporarily more sensitive to evoked response signals:

at the moment that a stimulating pulse is delivered to the heart, the sense amplifier is switched to a lower frequency bandpass to render it more responsive to an evoked potential (for example, the T wave).

(Stotts at col. 3, lines 19-23 (emphasis added).) Thus, Stotts expressly teaches directly away from these claims. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Also, regarding claim 4, Applicant cannot find in Stotts any disclosure, teaching, or suggestion of "the sensing circuit is configured such that the bandwidth decreases to a second bandwidth value, from a first bandwidth value, upon occurrence of the event," as recited in claim 4. Instead, Stotts merely refers to shifting a bandpass center frequency downward, not to decreasing bandwidth of the passband of the bandpass filter. (See Stotts at col. 4, lines 52-52.) Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Similarly, regarding claim 5, Applicant cannot find in Stotts any disclosure, teaching, or suggestion of "the sensing circuit is configured such that the bandwidth increases from the second bandwidth value toward the first bandwidth value during the first time period," as recited in claim 5. Instead, Stotts merely refers to shifting a bandpass center frequency downward, not to increasing bandwidth of the passband of the bandpass filter. (See Stotts at col. 4, lines 52-52.) Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Regarding claim 7, Applicant cannot find in Stotts any disclosure, teaching, or suggestion of "the sensing circuit is configured such that an attenuation of a T-wave of the heart signal during the first time period is greater than or equal to the attenuation of the T-wave immediately after expiration of the first time period, as recited in claim 7. Instead, Stotts works the opposite, by increasing responsiveness to the T-wave evoked potential, as explained above. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Regarding claim 11, Applicant cannot find in Stotts any disclosure, teaching, or suggestion of the sensing circuit including an automatic gain control (AGC) circuit, as recited in claim 11. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Regarding claim 13, Applicant cannot find in Stotts any disclosure, teaching, or suggestion of the highpass pole frequency increasing to a second frequency value, from a steady-state first frequency value, in response to detection of the therapy event or a QRS complex, as similarly recited in claim 13. Instead, Stotts works the opposite—by shifting its passband downward to detect the evoked response, Stotts would necessarily shift the highpass pole frequency downward as well. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Regarding claim 14, Applicant cannot find in Stotts any disclosure, teaching, or suggestion of the sensing circuit being configured such that the highpass pole frequency gradually decreases from the second frequency value toward the first frequency value during the first time period, as presently similarly recited in claim 14. Instead, Stotts apparently abruptly shifts its frequency response, as explained above. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Regarding claim 17, Applicant cannot find in Stotts any disclosure, teaching, or suggestion of the sensing circuit being configured such that the first time period is initiated by at least one of the therapy event and evoked and intrinsic QRS complexes, and the lowpass pole frequency gradually increases from the second frequency value toward the first frequency value during the first time period. Instead, Stotts apparently abruptly shifts its frequency response, as explained above. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Regarding claim 21, Applicant cannot find in Stotts any disclosure, teaching, or suggestion of the sensing circuit being configured such that the gain gradually increases, from the second gain value toward the first gain value during the second time period. Instead, Stotts apparently abruptly shifts its gain. (See Stotts at col. 4, line 64.) Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

Regarding claims 39 and 43, Applicant cannot find in Stotts any disclosure, teaching, or suggestion of the gradual adjustment of the frequency bandwidth comprising a substantially continuous function of the elapsed time, as similarly recited in these claims. Instead, Stotts' abrupt switching would necessarily introduce a discontinuity in the frequency bandwidth as a function of time, as explained above. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

§ 103 Rejection of the Claims

Claims 8-10 were rejected under 35 U.S.C. § 103(a) as being obvious Stotts et al. (U.S. Patent No. 5,161,529). Applicant respectfully traverses this rejection on the grounds that no prima facie case of obviousness presently exists with respect to these claims, because Applicant cannot find all elements presently recited or incorporated in these claims in Stotts and/or the reasoning of the Office Action, for the reasons discussed above with respect to the § 102 rejection.

Further, the Office Action admits that "Stotts et al. discloses the claimed invention except for the range of the first time period." (See Office Action at 4.) Instead, the Office Action asserts that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the range of time for the first time period . . . [to] provide the predictable results of modifying the treatment to meet specific patient needs." (See id.)

However, Stotts is intended to detect an evoked potential occurring in response to a cardiac stimulation—which Stotts expressly defines as including a T-wave. (See Stotts at col. 3, lines 22-23.) Stotts desires to detect an evoked potential occurring with 10-30 milliseconds following delivery of a pace. (See Stotts at col. 4, line 46.)

By contrast, claims 8-10 of the present patent application recite a clinically very different time period (e.g., 250-500 milliseconds) that can be used for a clinically very different

purpose—the time periods recited in claims 8-10 can be sufficiently long so as to allow the ventricle to repolarize (allow a T-wave to occur) while the sensitivity of the sensing circuit is still reduced. This clinically significant benefit is explained in an example provided in the specification of the present patent application. (See Application at page 9, lines 10-15.)

Consider: if Stotts teaches detecting a T-wave, and the present patent application teaches ignoring it, can the different time intervals involved really be regarded as mere routine optimization, as asserted by the Office Action? Applicant respectfully submits, of course not.

In sum. Applicant respectfully requests withdrawal of this rejection of claims 8-10.

Reservation of Rights

In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action, however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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Date March 30, 2009 Bv

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1496, Alexandri, VA 22313-1450 on March 30, 2009.

Kate Gannon

Name

Signature